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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/052,855	03/31/98	BILLING-MEDEL	P 6064.US.P1

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EXAMINER	
JOHNSON, N	
ART UNIT	**PAPER NUMBER**
1642	26

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/052,855	Applicant(s) Billing-Medel
	Examiner Nancy Johnson	Group Art Unit 1642

☒ Responsive to communication(s) filed on *Apr 11, 2000*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-43* is/are pending in the applicat

Of the above, claim(s) *1-9, 17-24, 26-29, 31-34, 36, and 37* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *10-16, 25, 30, 35, and 38-43* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

1. Claims 10, 11, 15, 30 have been amended.

Claims 40-43 have been added.

Claims 1-43 are pending.

Claims 1-9, 17-24, 26-29, 31-34, 36-37 remain withdrawn from examination.

Claims 10-16, 25, 30, 35 and 38-43 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 10-16, 25, 30, 35, 38-43 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility.

Claims 10-16, 30, 35, 40-43 are drawn to polynucleotides (and vectors, host cells, recombinant expression systems and test kits comprising said polynucleotides and methods of producing a polypeptide product from said polynucleotides) that "specifically bind" and are 70% (or 90%) identical to a sequence selects from the group consisting of SEQ ID NO:1; SEQ ID NO:2; SEQ ID NO:3; SEQ ID NO:4; SEQ ID NO:5; SEQ ID NO:6; SEQ ID NO:7; SEQ ID NO:8; SEQ ID NO:9; SEQ ID NO:12; SEQ ID NO:13; fragments comprising at least about 10 contiguous nucleotides of any of Sequence ID NOs 1, 2, 3, 4, 5; and complements thereof. Claim 39 is drawn to "polynucleotide comprising DNA having at least 50% identity with SEQ ID NO:12 or SEQ ID NO:13. Claim 25 is drawn to a method of producing a polypeptide, said polypeptide encoded by a polynucleotide that encodes an amino acid sequence at least 50% identical to an amino acid selected from the group consisting of SEQ ID NO:24; SEQ ID NO:25; SEQ ID NO:26; SEQ ID NO:27; SEQ ID NO:28; and fragments comprising at least 8 amino acids of SEQ ID NO:24 or SEQ ID NO:25. Claim 38 is drawn to polynucleotide which encodes a polypeptide having at least 60% identity with SEQ ID NO:24 or SEQ ID NO:25.

Thus, the claims are drawn to a broad range of polynucleotide sequences based on SEQ ID NOs 1-9, 12 and 13 or those that encode SEQ ID Nos 24-28. The specification discloses SEQ

ID NO:1-9, all of which are partial sequences of cDNA inserts ("EST"or expressed sequence tags) of 187-287 nucleotides in length, and SEQ ID NO:12 and SEQ ID NO:13 which are the full length sequence and consensus sequences comprising SEQ ID NO:1-9, respectively. The specification asserts the following utility for the claimed inventions, "as markers of GI tract disease, particularly GI tract cancer." However, the specification does not disclose any diseases or conditions known to be associated with the cited polynucleotide sequences. Further, even though the specification discloses that the consensus sequence and fragments thereof are found more than 12 times more often in GI tract tissue than in non-GI tract tissue, such tissue-specific expression does not rely on specific properties of the polynucleotide sequences and is not considered to be a specific or substantial utility. Thus, the claimed polynucleotides are not supported by either a specific, substantial and credible asserted utility or a well-established utility.

Claims 10-16, 25, 30, 35, 38-43 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

4. Claims 10-16, 25, 30, 35 and 38-43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn around polynucleotide sequences 70% (or 90%) identical to the polynucleotide sequences of SEQ ID NO:1-9, 12 or 13, "fragments consisting of at least about 10 contiguous nucleotides of SEQ ID NO:1-5, polynucleotides that encode amino acid sequences 50% identical to SEQ ID NO:24-25 or fragments comprising at least about 8 contiguous amino acids of SEQ ID NO:24 or 25. Thus, the claims encompass polynucleotide sequences that have a recited degree of change as compared to the reference nucleic acid sequences SEQ ID NO:1-9 and 12-13. None of these sequences meets the written description provision of 35 USC 112, first

paragraph. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required.

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

5. Claims 10-16, 30, 35, 38, 40-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10, 11, 15 and 30 are vague and indefinite in the recitation "specifically binds." All portions of the specification cited in support of this amended recitation discuss very broadly "specific binding interactions," including the hybridization of DNA, the binding of antibodies with an antigen, the interaction of receptors with ligands and the physical immobilization of materials to solid support. The specification states "two different molecules where one of the molecules, through chemical or physical means, specifically binds to the second molecule." Other than the base pairing interaction that occurs during the hybridization of nucleic acid molecules, it is unclear what physical or chemical means of specifically binding are encompassed by the claims.

Claim 38 is vague and indefinite in the recitation "a fragment at least 10 nucleotides thereof, which codes for a polypeptide which comprises an amino acid sequence having at least 60% identity with SEQ ID NO:24 or SEQ ID NO:25." It is unclear how fragments of such small size can encode polypeptides 60% identical overall to SEQ ID NO:24, which is 223 amino acids in length, or SEQ ID NO:25, which is 38 amino acids in length.

6. The rejection of claims 10-14, 25 and 30 under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement commensurate with the scope of the claims is withdrawn.

7. Sequences exactly identical to SEQ ID NO:1-9, 12, 13, 24 or 25 are not found in parent application 08/828,489, filed 3/31/97. Thus, for the application of the art, priority is granted only to the instant filing date, 3/31/98.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

9. Claims 25 and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by 5,733,748 (filed 6/6/95). U.S. Patent 5,733,748 ('748 patent) discloses SEQ ID NO:6 which encodes the amino acid sequence SEQ ID NO:7, an amino acid sequence which is 100% identical to residues 89-223 of SEQ ID NO:24 (see attached copy of search results). The '748 patent also discloses a method of producing a polypeptide product from said polynucleotide. Thus, the '748 patent discloses a method and a purified polypeptide that is the same as that claimed in claims 25 and 38.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Johnson whose telephone number is (703) 305-5860. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa , can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June 16, 2000

NANCY A. JOHNSON, PH.D
PRIMARY EXAMINER